EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114293047-46-01/F Helsinki, 27 February 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For the product from the burning of a combination of carbonaceous materials, CAS No NS (EC No 931-597-4), registration number: [redacted]

Addressee: [redacted]

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for the product from the burning of a combination of carbonaceous materials, CAS No NS (EC No 931-597-4), submitted by [redacted] (Registrant).

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation). The scope of this compliance check is limited to the standard information requirement of Annex X, Section 8.7.2 of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000tonnes or more per year.

This decision does not take into account any updates submitted after 4 September 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 20 June 2013.

On 26 September 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. The draft decision was based on submission number [redacted]

Within 30 days, ECHA did not receive comments from the Registrant on the draft decision.

On 4 September 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 October 2014 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and did not change Section II of the draft decision, while Section III was amended.

On 20 October 2014 ECHA referred the draft decision to the Member State Committee.

By 10 November 2014, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposal for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposal for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 8-11 December 2014, a unanimous agreement of the Member State Committee on the draft decision was reached on 10 December 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex X of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route;

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **7 March 2016**.

Notes for consideration by the Registrant:

In light of the comments made by the Registrant, ECHA points out that the Registrant may adapt the testing requested above according to the specific rules outlined in Annexes IX to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a sound scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Authorities of the Member States for enforcement.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vii), 12(1) e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annex X of the REACH Regulation.

- Pre-natal developmental toxicity study (Annex IX 8.7.2.)

A "Pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

The Registrant has justified the proposal for adaptation with a reference to Annex XI, section 3.1., according to which testing ... "may be omitted, based on exposure scenario(s) developed in the Chemical Safety Report".

ECHA points out that section 3.1. of Annex XI shall be regarded as an introduction to paragraph 3.2. of the same Annex, that specifies which criteria need to be met by the Registrant in order adapt the relevant information requirements. In the dossier the Registrant has not justified nor documented any of the criteria that need to be fulfilled pursuant to section 3.2. (a) to (c).

Therefore, since the Registrant has not provided sufficient data to show that any one of the criteria given in Annex XI, 3.2 REACH Regulation is met, the adaptation of the information requirement proposed by the Registrant cannot be accepted.

The Registrant has also justified the proposal for adaptation with a reference to Annex IX, section 8.7., column two.

According to Annexes IX and X 8.7., Column 2, the study does not need to be conducted if the substance is of "low toxicological activity", "no systemic absorption occurs" and there is "no or no significant human exposure".

The Registrant has however not documented that the conditions of that adaptation possibility are fulfilled. According to the Registrant, the substance is of low toxicological activity. In the 28-day oral toxicity study in rats at dose levels up to 2000 mg/kg bw/day, the only effect of slight toxicological relevance was temporarily increased serum urea levels in males at doses 1000 mg/kg and above. However, according to the information given in the dossier, some constituents of the substance (e.g. Pb) are bioavailable and have been absorbed. Furthermore, while the Registrant has referred to the use of certain protective measures, it has not been documented with relevant data that there is no or no significant human exposure.

Therefore, since the Registrant has not provided sufficient information to show that the conditions of the adaptation in Column 2 of Annex IX, 8.7 are met, the adaptation of the information requirement proposed by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

In a proposal for amendment one Member State considered that the request for a pre-natal developmental toxicity study should be rejected as the most significant human health hazards of the registered substance relate to lead content and risk management should take into account the potential for lead exposure. The Member State furthermore considered that human health hazards of lead exposure are well understood and tightly regulated within the EU and that it is unclear that the requested study will provide any additional useful information for risk management of the registered substance and the requested test should be rejected.

ECHA first notes that the Registrant has neither proposed in its registration dossier the adaptation outlined by the Member State nor has it provided adequate and reliable documentation in its dossier to support the proposed adaptation.

Furthermore, ECHA notes that pursuant to Annex I, section 0.5 of the REACH Regulation "in accordance with section 3 of Annex XI in some cases it may not be necessary to generate missing information because risk management measures and operational conditions which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely".

In the present case ECHA notes that the risk or hazard posed by the registered substance is not "well-characterised", because the studies that would characterise the risk are not provided, not even in a weight of evidence approach. Indeed, the risk management measures referred to by the Member State only concern one constituent of the registered substance, while the other constituents (which are also hazardous in nature) remain uncharacterised.

The Registrant has in fact not covered the toxicity of other metals, e.g. cadmium, arsenic, zinc, manganese, and aluminium, which are constituents of the registered substance. The presence of these metals, although they are only found in minute concentrations (3-22 ppm; while the lead concentration is 180 ppm) makes the direct application of the lead toxicity to the registered substance scientifically not plausible.

Moreover, ECHA considers that in the registration dossier, a developmental toxicity study has neither been provided for the registered substance nor for any constituent of it.

Finally, not all the literature on the toxicity of lead has been covered and referred to in the dossier. More notably, the Registrant does not propose that the toxicity of ash can be addressed and covered by the studies made with lead, as the registrant has provided a sub-acute study and one low-quality reproductive toxicity study, which are both made with the registered substance, "mixed ash", as referred to in the study record.

In his comments to the proposal for amendment, the Registrant agreed with it, and provided new information on lead which was not included in the registration dossier prior to the date upon which ECHA notified the draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation. The new information on lead consists of biomonitoring data, a reference to a PNDT-study on lead acetate, and an analysis of the potential to administer the registered substance at sufficient doses to obtain lead blood concentrations at toxic levels. ECHA considers this data informative but not sufficient by itself, as it does not address the uncertainties on the hazard characterization of the registered substance as mentioned in response to the proposal for amendment, nor that the Registrant properly controls the risks of all uses identified in the registration dossier. Moreover, the new information is not available in the dossier in a form of a justified adaptation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for these adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2. of the REACH Regulation.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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